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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,532	01/25/2002	Jeffrey A. Lyon	003/240/SAP	2344

7590 12/14/2006

ATTN: MCMR-JA (Ms. Elizabeth Arwine-PATENT ATTY)
U. S. Army Medical Research and Materiel Command
504 Scott Street
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EXAMINER	
BASKAR, PADMAVATHI	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 12/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/057,532	LYON ET AL.	
	Examiner	Art Unit	
	Padmavathi v. Baskar	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *18 September 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5 and 7-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5 and 7-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Amendment

1. The response filed on 9/18/06 has been entered into the record.

Status of Claims

2. Claims 1, 3 and 5 have been amended.

Claims 2, 4 and 6 are cancelled.

Claims 1, 3, 5 and 7-16 are pending and are under examination in the application.

Claim Rejections - 35 U.S. C. § 112, second paragraph withdrawn

3. In view of amendment to the claims, the rejection under 35 U.5.C. 112, second paragraph is withdrawn.

Claim Rejections - 35 USC 102 maintained withdrawn

4. The rejection of claims 1, 3 and 5 are rejected under 35 U.S.C. 102(e) as being anticipated by Hui et al 2003, US 6,660,498 is withdrawn.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negative by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1, 3, 5 and 7-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Angov et a1.(1999) , Process development for clinical grade *Plasmodium falciparum* MSPI-

42(3D7) expressed in *E. coli*, American Journal of Tropical Medicine and Hygiene, 61 p. 207 (48th Annual Meeting of the American Society of Tropical Medicine and Hygiene, Washington, D.C. 28 November - 2 December 1999, Abstract 133) in view of Hui et al 2003, US 6,660,498.

The claims are drawn to a vaccine comprising a C-terminal 42 kD fragment of merozoite surface protein-1 (MSP-142) from P. falciparum 3D7as set forth in SEQ ID NO:7, that is recombinantly expressed in E. coli as a soluble protein that retains its native structure, and an adjuvant of different combinations and administration of different doses and routes . Claims are also drawn to a method for inducing an immune response to malaria in a subject or a method for inducing a protective immune response to malaria in a mammal using said vaccine

Angov et al teach recombinant $MSP1_{42}$ protein from *P.falciparum* 3D7 produced in *E.coli* using pET T7 driven promoter-expression system that results in soluble $MSP1_{42}$. The final lyophilized product is stable and antigen is folded correctly and contain T-helper epitopes that will enhance induction of humoral responses. Mice seroconverted following immunization with recombinant $MSP1_{42}$ (see IDS, 9/30/03). In the absence of evidence to the contrary the disclosed prior art protein and the claimed protein , C-terminal 42 kD fragment of merozoite surface protein-1 (MSP-142) from P. falciparum 3D7as set forth in SEQ ID NO:7are the same. Since the Office does not have the facilities for examining and comparing applicants' P. falciparum 3D7as set forth in SEQ ID NO:7 and the prior art protein, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

However, the art does not teach using said protein in a vaccine composition with an adjuvant and method of inducing immune response or protective immune response.

Hui et al disclose a vaccine composition comprising *P.falciparum* 3D7 merozoite surface protein, MSP-1_{42} in an adjuvant (see, column 7, lines 38-65 and columns 2-3). The prior art also discloses a method for inducing an immune response and a method of inducing protective immune response comprising administering said vaccine preparation comprising an adjuvant to an individual (column 3, line 24 through column 4, line 5).

It would have been prima facie obvious to one of ordinary skill in the art at the time invention was made to use the readily available technology of making protein in an expression system *E.coli* as taught by Angov et al because the art suggests product produced in *E.coli* is a soluble form and antigen is folded correctly and contain T-helper epitopes that will enhance induction of humoral responses. Therefore, an artisan of ordinary skill would have been motivated to produce the recombinant product in *E.coli* because Angov et al clearly suggests that the protein obtained from E.coli is vaccine grade product and could be used as a vaccine candidate antigen. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to make the protein in *E.coli* as taught by Angov et al and use that in a vaccine composition with an adjuvant of Hui et al . The adjuvant combinations, adminsitration of multiple doses and routes of immunizations recited in the claims are conventional in the vaccine art. The claimed invention is a prima facie obvious over Angov et al in view of Hui et al absent any convincing evidence to the contrary.

Remarks

7. No claims are allowed.

Conclusion

8. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600

Padma Baskar Ph.D.

SUSAN UNGAR, PH.D
PRIMARY EXAMINER